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ActuatedMedical.com

Certified...

- + ISO 13485:2016
- + Medical Device Single Audit Program (MDSAP)
- + Women's Business Enterprise (WBE)
- + Women-Owned Small Business (WOSB)

FOR IMMEDIATE RELEASE:

January 9, 2024

Actuated Medical Selected to Accelerate Neurological Technology Breakthroughs through NIH Blueprint MedTech Contract

[Bellefonte, PA] — Actuated Medical, Inc. is pleased to announce that it has been selected as a Contract Research Organization (CRO) under the National Institutes of Health (NIH) Blueprint MedTech (BPMT) initiative with a potential contract value of \$35M over 5 years.

100 million people in the U.S. suffer from neurological diseases like Parkinson's and Epilepsy. The problem is growing. The U.S. expends \$800 billion annually on the treatment of neurological conditions. Recognizing the need for better diagnosis and treatments, the NIH has launched the BPMT program. The BMPT initiative assists innovators, facilitating moving their cutting-edge medical device developments toward Regulatory Approvals and commercialization, with support and resources that small companies and university researchers often lack.

Actuated Medical has been selected to offer extensive support to BPMT awardees that are working with the MedTech Hubs of CIMIT in Boston and NeuroTech Harbor in the Baltimore/DC area. This exciting partnership reinforces Actuated Medical's commitment to advancing healthcare through groundbreaking research, development, and manufacturing.

"We are thrilled to have been selected as a CRO for the BPMT initiative," said Maureen L. Mulvihill, Actuated Medical President & CEO. "This program will allow us to support entrepreneurial researchers moving their groundbreaking devices toward first-in-man studies to transform treatment of neurological conditions like stroke, Epilepsy, and Parkinson's Disease."

The Actuated Medical BPMT contract provides comprehensive support to multiple BPMT grantees. This assistance encompasses the completion of biocompatibility studies, in vivo preclinical testing with adherence to good laboratory practice (GLP) guidelines, and sterilization and shelf-life testing crucial for advancing medical device development. Actuated Medical's commitment extends to supporting research protocol development, facilitating in-house staff training, and conducting all necessary tests vital for biocompatibility, sterilization, and preclinical safety studies. These findings will serve as the cornerstone for informing regulatory filings, including Investigational Device Exemptions (IDEs), and eventual marketing approval by the US Food and Drug Administration (FDA).



This project has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N95023D00022.

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About Actuated Medical:

Actuated Medical is a medical device product innovator with a portfolio boasting seven FDA 510(k) clearances, over 41 US and International patents, and three products making waves in early sales. Their focus is on research equipment and medical devices, which include an active-motion component, that impact neuroscience, gastrointestinal, critical care, and pediatrics. The company operates from a cutting-edge 20,000sq.ft. facility in central Pennsylvania, with ISO 13485 and WOSB certifications underscoring their commitment to quality.

About NIH Blueprint for Neuroscience Research:

https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-medtech/resources

About Center for Innovative NeuroTech Advancement (CINTA):

https://www.cimit.org/web/center-for-innovative-neurotech-advancement

About and NeuroTech Harbor (NTH):

https://neurotechharbor.org/

For media inquiries, please contact: Maureen L. Mulvihill, Ph.D. by phone at 814-355-0003 or email at info@actuatedmedical.com.

Additional information can be found by visiting: actuatedmedical.com actuatedneuroscience.com

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